

# TITLE OF THE INVENTION

# Computerized Risk Management Module For Medical Diagnosis

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims priority of provisional applications filed on October 31, 2000, Serial No. 60/244,496, attorney docket no. 12917US01, and Serial No. 60/245,255, filed November 2, 2000, and is a continuation of application Serial No. 09/705,058, filed November 2, 2000, and also entitled: "Computerized Risk Management Module for Medical Diagnosis," naming the same inventors. The entire text and drawings of the applications identified above are incorporated here by reference.

## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

**[0002]** Not Applicable.

## BACKGROUND OF THE INVENTION

**[0003]** This invention generally relates to apparatus and methods for improving medical care. (“Medical care” is broadly defined here to include both medical diagnosis and therapeutic treatment of a patient.) This invention relates more particularly to such apparatus and methods that can be used by a health care professional to avoid making the kinds of professional mistakes that can lead to a significant risk of legal liability.

**[0004]** “Health care professionals” is used broadly here to refer to anyone who participates in the diagnosis or treatment of medical problems. For example, medical doctors, dentists, nurses, nurse-practitioners, medical technologists, physical therapists, and other health

[illegible]

workers that assist in examination of patients, diagnosis, or treatment are all included by this term.

**[0005]** A health care professional diagnoses an illness by collecting and evaluating information about the patient, then determining what disease or condition best fits the information. The information gathered from the patient usually is processed to reach a diagnosis by using a protocol learned during the professional's professional training and modified and updated by his or her medical experience. The protocol is an ordered process by which a health care professional ascertains information that allows the professional to rule out possible diseases until enough information is gathered to eliminate all but the diagnosed condition. Alternatively, the protocol may end when an appropriate treatment is identified. Recently, medical associations, health maintenance organizations, and hospitals, among others, have prescribed protocols. Employed health care professionals in particular are often subject to mandated protocols.

**[0006]** One problem in the field of medicine is how to improve diagnostic protocols to take into account advances in medical knowledge. A related problem is how to ensure that health care professionals update their skills to take advantage of advances in medical knowledge. Still another problem is how to expedite the diagnosis and treatment of certain conditions that should be treated quickly, so treatment can begin soon enough to be most effective.

**[0007]** U.S. Patent No. 6,095,973 discloses a data processing system and method for evaluating the treatment of chest pain patients in a medical facility. The system accepts actual patient treatment information from a clinical setting and predetermined appropriate patient treatment information from a source of that information. The system compares the actual patient treatment information to the treatment that is considered

appropriate, and reports the results of its comparison so that the medical facility is able to improve its treatment of chest pain patients.

**[0008]** U.S. Patent No. 6,029,138 discloses a decision support system for the selection of a diagnostic test or therapeutic intervention, which are both called "studies" in that patent. The system identifies how often significant results were obtained in prior studies having the same indications. The number of studies performed for which results were significant for the same indications, as a proportion of the total number of studies performed for the same indications, is provided as feedback to the ordering physician. This patent states that decision support can be enhanced by using data extracted from existing scientific literature respecting how appropriate a study is, given the indications reported by the ordering physician.

**[0009]** U.S. Patent No. 4,857,713 discloses a program for reducing hospital errors in the delivery of medications, goods, services or procedures in patient treatment. The patient wears a wrist identification band with a preprinted computer-readable code. Unit doses of medications or goods available for administration are provided with preprinted computer-readable codes. A portable computer is loaded with a physician's orders for medications, goods, services or procedures for specific patients. Before medications, goods, services or procedures are administered to a patient, hospital personnel will scan the machine-readable codes on the patient's identification band, and then on the unit dose(s) of the medications, goods, services, or procedures. The portable computer will compare these readings with the doctor's orders and other internal files as required and verify that the administration of the identified medications, goods, services or procedures is either correct or not correct.

**[0010]** In the system described in U.S. Patent No. 5,517,405, a user enters a medical condition and a proposed medical procedure to treat

the condition. In one mode, the system dynamically generates questions in response to previous information provided by the user to determine and then communicate whether the proposed treatment is appropriate.

**[0011]** U.S. Patent No. 5,732,397 describes an automated system for use in decision-making processes which is said to improve the quality and consistency of decisions made. Medical decisionmaking is discussed, for example, from col. 3, line 49 to col. 4, line 6, and from column 5, line 47 to col. 8, line 47.

**[0012]** U.S. Patent No. 5,772,585 discloses a common user interface to allow different medical personnel access to centralized files regarding patients. The system allows health care professionals to concurrently record examination and diagnosis notes in a database during patient examination. The system is said to provide a common graphic user interface capable of accessing all necessary tasks through a common database structure. The system displays allergy warnings and records a diagnosis based on the progress notes.

**[0013]** U.S. Patent No. 5,832,450 describes an electronic medical record system that stores data about individual patient encounters in a convenient form.

**[0014]** U.S. Patent No. 5,845,255 describes an electronic prescription creation system for physician use that includes an adverse indication review and online access to comprehensive drug information including scientific literature. This patent also provides an extensive background on the problems of automating patient data record systems for physicians.

**[0015]** U.S. Patent No. 5,911,132 discloses diagnosing and treating patient diseases using a epidemiological database containing medical, personal or epidemiological data relevant to a presented set of symptoms, test results, a diagnosis, etc. For example, if a food poisoning

epidemic breaks out in a particular place, the epidemiological database computer facility will begin to receive from that place epidemiological transaction records in which "food poisoning" is listed as being at least the tentative diagnosis. When this happens, the computer facility returns an electronic data communication to a physician submitting such a patient transaction record a suggestion that food poisoning be considered as a likely source of the patient's problems.

**[0016]** U.S. Patent No. 5,915,240 discloses a context-sensitive medical lookup reference computer system for accessing medical information over a network.

**[0017]** U.S. Patent No. 5,924,074 discloses a medical records system that is said to create and maintain all patient data electronically. The system captures patient data, such as patient complaints, lab orders, medications, diagnoses, and procedures, at its source at the time of entry. Authorized healthcare providers can access, analyze, update and electronically annotate patient data even while other providers are using the same patient data record. The system is said to permit instant, sophisticated analysis of patient data to identify relationships among the data considered. Moreover, the system is said to include the capability to access reference databases for consultation regarding allergies, medication interactions and practice guidelines.

**[0018]** U.S. Patent No. 5,953,704 discloses a system in which a user inputs information related to the health condition of an individual. Guideline treatment options are identified by the system. The user is also said to be able to input actual or proposed and final recommendation treatments for the individual. The patent states that the resulting comparative information can be used to modify the actual or proposed treatment.

**[0019]** U.S. Patent No. 6,022,315 discloses a system and method for providing computerized, knowledge-based medical diagnostic and treatment advice to the general public over a telephone network or a computer network.

[0020] The patents discussed above are not understood to disclose a system that communicates to a health care professional carrying out a diagnosis that a certain symptom, combination of symptoms, or other patient information recorded by the physician is associated with an increased risk of a missed medical care opportunity leading to a less favorable patient outcome. (A “medical care opportunity” is defined as an opportunity to correctly or more quickly diagnose or treat the patient’s condition and thus provide a better patient outcome.) Nor does the disclosed apparatus communicate to the health care professional special steps to take to avoid the missed medical care opportunity.

## BRIEF SUMMARY OF THE INVENTION

**[0021]** One aspect of the invention is apparatus for improving the medical care of patients. The apparatus includes an input device, a medical risk database, a data processor, and a communication device.

**[0022]** The input device can be any device that is useful for entering medical data presented by a patient. Data entered in the input device defines a patient data record.

**[0023]** The medical risk database associates certain patient data, which increases the risk of a missed medical care opportunity, with additional medical care. The additional medical care is predetermined action that reduces the risk of a missed medical care opportunity, despite the presentation of the patient data.

**[0024]** The data processor is programmed to compare the patient data record with the medical risk database. This comparison is carried out

to identify patient data in the record that increases the risk of a missed medical care opportunity.

**[0025]** The communication device responds to the identification of patient data that increases the risk of a missed medical care opportunity. The communication device responds by communicating to a health care professional additional medical care. The additional medical care is selected to reduce the risk of a missed medical care opportunity.

**[0026]** Another aspect of the invention is an interactive method a health care professional can use for avoiding medical risk while the health care professional is providing medical care to a patient.

**[0027]** The health care professional records medical data presented by the patient in a data storage device, forming data records.

**[0028]** The health care professional has access to a medical risk database maintained on a data storage medium. The database associates certain medical data with additional medical care. The certain medical data is data that increases the risk of a missed medical care opportunity. The additional medical care is something that can be done to reduce the risk of a missed medical care opportunity, despite the presentation of the certain medical data.

**[0029]** A data processor is used to compare the medical data presented by the patient with the medical data in the medical risk database to identify whether medical data presented by the patient is associated with a risk of missed medical care opportunity.

**[0030]** If medical information presented by the patient is associated with a risk of missed medical care opportunity, information about additional medical care that would reduce the risk of a missed medical care opportunity is presented to the health care professional.

**[0031]** Another aspect of the invention is an interactive diagnostic template for medical diagnosis. The template includes indicia (which can

be text, a symbol or icon, spoken information, or other identifying information) indicating potential symptoms contributing to a diagnosis. Indicia are provided for at least two different kinds of symptoms.

[0032] A first group of symptoms are prompted symptoms that are recommended to be checked to properly document the diagnosis. A second group of symptoms are optional symptoms that can be checked at the option of an attending health care professional.

[0033] Symbols are associated with the prompted symptoms. The symbols have a first condition when the evaluation of a prompted symptom has not yet been documented and a second, visibly distinct condition when evaluation of the prompted symptom has been documented. For example, but without limitation, the first condition of the symbols can be a representation of a lit red light, and the second condition of the symbols can be a representation of a lit green light. The medical professional can be advised that she or he can pass by a symptom if a green light is lit, but that it is recommended that he or she stop and evaluate a symptom if a red light is lit.

[0034] Optionally, additional indicia can be provided indicating at least one conditionally prompted symptom. A conditionally prompted symptom is prompted when at least a first other associated prompted symptom is present but not prompted if the other associated prompted symptom is absent. A symbol associated with the conditionally prompted symptom is activated only if the associated prompted symptom is documented. When the associated prompted symptom has been documented, the symbol for the conditionally prompted system is activated. It can have two conditions, again indicating whether the conditionally prompted symptom has been documented or not.

[0035] Still another aspect of the invention is an interactive diagnostic template for medical triage of a patient. The triage template is



a display presenting a list of acute emergencies that require immediate notification to a treating medical professional to avoid death or grave injury of the patient. The template presents a symbol associated with the acute emergency list that has a first condition prompting a triaging medical professional to evaluate whether any of the acute emergencies exists and a second, visibly distinct condition when the triaging medical professional has ruled out all of the acute emergencies. Alternatively, the symbol may be displayed next to smaller groups of conditions or individual conditions. The triage template or associated components presents a warning signal to the triaging medical professional, responsive to the documentation of an acute emergency, to notify a treating medical professional immediately.

**[0036]** Even another aspect of the invention is an interactive diagnostic template for medical diagnosis. This template again includes indicia indicating potential symptoms contributing to a diagnosis. A key information icon is associated with at least one potential symptom, indicating that additional information pertinent to the potential symptom is available for review upon request. An input device is provided to allow the medical professional using the template to request a display of the additional information associated with the icon.

**[0037]** Some examples of additional information that can be provided include:

- an anatomical drawing of the site of the symptom associated with the icon;
- a diagnostic score relating to the symptom associated with the icon;
- an update on the standard of care relating to the symptom associated with said icon; or
- information on how to test for the symptom associated with the icon.

## BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

[0038] Figure 1 is a schematic view of one example of a medical charting system suitable for carrying out the present invention.

[0039] Figure 2 shows a portion of an exemplary medical diagnostic template for use with the system of Figure 1 when diagnosing chest pain.

[0040] Figure 3 is similar to Figure 2, but shows the template modified to display an activated medical risk icon when an entry is made on the template that the patient has chest pain radiating to the back.

[0041] Figure 4 is a pop-up legend presented by the system when the activated medical risk icon is queried to determine the nature of the medical risk.

[0042] Figure 5 is a schematic view of a portion of the chest pain electronic medical record template with nine sets of red light, green light prompts. The prompts are all red, in their condition when the template is first displayed but has not yet been modified by entering information about symptoms.

[0043] Figure 6 is a schematic view of a later portion of the same template shown in Figure 5. No red light, green light prompt is initially displayed next to "Bilat. BP's" (bilateral blood pressures) on the template as initially displayed.

[0044] Figure 7 is a schematic view of the chest pain electronic medical record template with the nine sets of red light, green light prompts all turned green. The "location" section has been marked to indicate that the pain is "substernal" and "radiating to back."

[0045] Figure 8 is a schematic view of a later portion of the same template shown in Figure 7. Now a red light, green light prompt is initially displayed next to "Bilat. BP's" (bilateral blood pressures) on the

template, responsive to the documentation of pain radiating to the back earlier on the same chart.

[0046] Figure 9 is a bar chart showing the results of a medical research study published in the Supplement to Annals of Emergency Medicine ACEP Research Forum, October 23-23, 2000, which is incorporated here by reference. Figure 9 demonstrates compliance with five historical elements of the chest pain evaluation using dictated medical records and the electronic medical record with red light green light prompting.

[0047] Figure 10 is a schematic view of a portion of the electronic medical record shoulder injury template prior to clicking on the key information icon for shoulder anatomy.

[0048] Figure 11 demonstrates the electronic medical record shoulder injury template after clicking on the key information icon for shoulder anatomy, displaying a drawing of shoulder anatomy.

#### DETAILED DESCRIPTION OF THE INVENTION

[0049] While the invention will be described in connection with one or more embodiments, it will be understood that the invention is not limited to those embodiments. On the contrary, the invention includes all alternatives, modifications, and equivalents as may be included within the spirit and scope of the appended claims.

[0050] The present inventors have discovered a previously overlooked source of information from which appropriate diagnostic protocols can be developed: the results of medical malpractice claims. Each malpractice claim represents a decision made by a patient that his or her medical care was not appropriate and harmed him or her.

[0051] For example, a course prepared by inventor Daniel J. Sullivan, M.D., J.D., *High-Risk Acute Care: The Failure to Diagnose*

(1998) identifies missed medical diagnoses as the principal cause of most malpractice suits. A missed medical diagnosis is defined here to include either the wrong diagnosis or a delayed diagnosis that leads to a materially worse patient outcome. This conclusion was reached by studying over 1000 medical malpractice suits to determine what caused the alleged malpractice and what could be done to avoid the alleged malpractice. *High-Risk Acute Care: The Failure to Diagnose* (1998) is incorporated here by reference.

[0052] Data about medical malpractice claims has limited scientific value because the data is strongly influenced by non-medical factors. These factors include the differences among the jurors and judges involved in different cases, how credible, worthy, or attractive the plaintiff, the physician, and other parties and witnesses may appear to be, and the skill of the respective lawyers. Other factors include differences in the laws of different states and the common unavailability of data for many claims, particularly claims that are resolved by private settlement instead of by public judgment.

[0053] The outcome of cases that proceed to trial depends on whether jurors agree that the care given to the plaintiff that led to the filing of the lawsuit was appropriate.

[0054] The amount of damage awarded to a successful plaintiff reflects the jury's impression of how much worse the patient outcome was economically, compared to what it should have been. By putting a dollar value on the harm suffered by the plaintiff, a jury verdict reflects how much importance should be attached to the alleged error in patient care. Again, the medical or scientific communities do not commonly gather this information. It can only be obtained from litigation results.

[0055] Despite its limited scientific value, information obtained by studying medical malpractice claims is vitally important to improve

diagnostic protocols. Medical malpractice claim experience largely reflects the attitudes of nonscientific, untrained, ordinary people. Such people have no connection with the scientific or medical worlds. The information they provide is not reflected in the usual diagnostic protocols, but often should be.

**[0056]** The present invention is not limited to information derived from medical malpractice claims. Any source of the required information, such as clinical experience, scientific experimentation, or the opinions of expert health care professionals is contemplated to be useful here.

**[0057]** One embodiment of the invention is the medical charting system 10 shown in Figure 1. The system 10 generally includes an input device 12, a medical risk database 14, a data processor 16, a communication device 18, and a data link 20.

**[0058]** The input device 12 can be any device that is useful for entering medical data presented by a patient. Data entered in the input device defines a patient data record.

**[0059]** One suitable input device is a cursor-moving device. A cursor moving device can be a pointing device such as a mouse, a track ball, a touchpad, a joystick, a voice-activated cursor directing program, a touch screen that moves a cursor responsive to finger or stylus placement or movement on the screen, etc.

**[0060]** Another suitable input device is a text entry device. A text entry device can be a keyboard for directly entering alphanumeric characters or other information directly. A non-alphanumeric keyboard can also be used, for example, a keyboard that has programmed keys directly representing the answers to medical questions indicative of medical information. A text entry device can be a text-generating device that converts spoken or handwritten words or characters into text entries. Two examples of text generating devices are a dictation program and the

stylus and tablet of a personal digital assistant. Another suitable text entry device is a scanner for reading or copying alphanumeric text, a bar code, or other indicia.

**[0061]** Another type of input device contemplated here is a mechanism for transmitting data to the system 10 from a medical instrument. Examples of suitable medical instruments are an electrocardiograph, an electroencephalogram (EEG), a blood pressure measuring instrument, a pulse monitor, a thermometer, a laboratory machine, an intravenous drug administration monitor, or any others.

**[0062]** Yet another type of input device contemplated here is a communication device allowing a patient to enter data on his or her own patient record. It is advisable to identify the information so entered as coming from the patient, and to limit access of the patient so only appropriate portions of the patient record, such as the portion input by the patient, can be accessed by the patient, and so pertinent information cannot be erased or changed by the patient after it is entered.

**[0063]** Even another type of input device contemplated here is a magnetic strip reader for extracting information from a card carried by the patient, such as medical information that could be recorded on a patient-carried emergency medical information card or insurance card.

**[0064]** Still another type of input device contemplated here is a communication link between preexisting patient records and the medical charting system 10, as for communicating medical history or previous medical treatment information.

**[0065]** The input device is used to input information about a patient. The information is stored as a patient data record 22. Examples are given below of patient record data that is pertinent to determining medical risks.

**[0066]** The patient data record 22 is physically embodied as data stored in any suitable medium. Suitable media include a hard drive, a floppy drive, a tape drive, a magnetic strip (as is often found on a credit card), or any other magnetic medium. Other suitable media include a CD, the internal memory of a computer, information written on paper or in microfiche form (either readable by a computer or by a physician), or in any other form, without limitation. The data in the patient data record 22 can be digital or analog data in text, numerical, graphic, audible, or any other form perceivable by a health care professional.

**[0067]** The patient data record 22 can be physically stored anywhere. For example, the patient data record 22 can be located in a drive of a portable computer, such as a notebook computer or a personal digital assistant, also providing the input device 12, data processor 16, and communication device 18 for the system. This could be a self-contained system carried by a health care professional and used for medical charting. Alternatively, the patient data record 22 can reside in a remote drive, computer, or server, as shown in Figure 1, and be accessed via a data link 20.

**[0068]** The medical risk database 14 associates certain patient data, which increases the risk of a missed medical care opportunity, with additional medical care. The additional medical care is predetermined action that reduces the risk. Examples of the information in the medical risk database 14 are provided below.

**[0069]** The medical risk database 14 is physically embodied as data stored in any suitable medium. Suitable magnetic media include a hard drive, a floppy drive, a tape drive, a magnetic strip such as the type often found on a credit card, or any other magnetic medium. Other suitable media include a CD, the internal memory of a computer, information recorded in paper or microfiche form (either readable by a computer or by

a physician), or in any other form. The data in the medical risk database 14 can be digital or analog data in text, numerical, graphic, audible, or other perceivable form. The media in which the medical risk database and patient data record can be stored can be the same medium or different media. Either of them can be stored in more than one place or in more than one medium. In a simple embodiment, the database 14 can be built into the template 24 shown in Figure 2 below, so entering certain patient data can prompt the presentation of a message that certain medical action is recommended.

**[0070]** The medical risk database 14 can be physically located anywhere. For example, the medical risk database 14 can be located in a drive of a notebook computer or personal digital assistant also providing the input device 12, data processor 16, and communication device 18 for the system. Alternatively, the medical risk database 14 can reside in a remote drive or computer, as shown in Figure 1, and be accessed via a data link 20.

**[0071]** The medical risk database 14 can be updated to reflect recent medical or legal experience. The updated database can be updated by providing a subscription CD or Internet download service, by updating a central database that is accessed by many health care professionals, or by any other effective method.

**[0072]** The data processor 16 is programmed to compare the patient data record 22 with the medical risk database 14. This comparison is carried out to identify patient data in the record 22 that increases the risk of a missed medical care opportunity. The data processor 16 can have any suitable form or configuration. It can be a dedicated microprocessor, a programmed general-purpose computer, or any other mechanical or electronic processing device. In a simple form of the



system, the data processor can be used simply to update the display to present a communication, responsive to the entry of certain patient data.

**[0073]** The communication device 18 is any type of device that communicates to a health care professional the presence of an increased medical risk, based on the identification by the data processor of information in the patient data record 22 that increases the risk of a missed medical care opportunity. The communication device 18 responds by communicating to a health care professional proposed additional medical care. The additional medical care is selected to reduce the risk of a missed medical care opportunity.

**[0074]** One suitable embodiment of the communication device 18, illustrated in Figure 1, is a video display operatively connected to the data processor 16 to display an indication of appropriate additional medical care. Another suitable embodiment of the communication device 18 is an alarm providing a signal perceptible to a health care professional. The alarm can be a visible warning, like a symbol on a graphical display or a warning light. The alarm can be an audible warning. The alarm can be a tactile warning, such as a signal sent to a vibrating pager, cellular telephone, or personal digital assistant worn or carried by the health care professional. The alarm can also be presented remotely, as to another health care professional who can attend to the alarm condition. In various embodiments, the alarm can be presented locally only, remotely only, or both locally and remotely.

**[0075]** The alarm can be arranged to ordinarily be selectively perceptible to a health care professional and not to the patient. For example, it can be presented as a visual display on a terminal screen that is selectively viewable from one angle, presented toward the health care professional, and not from another angle where the patient's eyes are positioned.



### Examples Of Associations In The Medical Risk Database

[0081] Examples 1-5 presented in tables at the end of this specification are examples of associations between patient data, increased medical risk, and one or more proposed medical responses that can optionally be made by the medical risk database 14. Two examples of proposed medical responses are diagnostic steps, as shown in several of the examples, or treatment steps, shown for example in the Neck Pain table of Example 2.

[0082] The associations presented here are merely exemplary. A skilled health care professional who is familiar with the present disclosure and investigates medical liability results can readily find additional or alternative associations of the same type, useful for addressing the same or other medical conditions. Medical risk information is available from Daniel J. Sullivan, M.D., J.D., *High-Risk Acute Care: The Failure to Diagnose* (1998). This publication is incorporated by reference. A medical risk database incorporated in the PulseCheck® medical charting system is commercially available from IBEX Systems Group, Ltd. sometimes known as IBEX Healthdata Systems, 5600 N. River Road, Suite 150, Rosemont, IL 60018. The templates and medical risk data of the PulseCheck® medical charting system are incorporated by reference here.

[0083] No representation is made that a health care professional should always follow the proposed advice, since it is not wise to rely solely on a preprogrammed database, unassisted by the judgment of a health care professional. The purpose of the medical risk database is simply to provide timely information to the health care professional that identifies and addresses a risk as it is presented.

## Communication of Medical Risk

[0084] Figure 2 shows a portion of an exemplary diagnostic template 24 that can be displayed on the communication device 18 when diagnosing a patient who complains of chest pain. The template 24 is shown in its initial condition, before a health care professional begins to respond to questions raised by the template. For example, the template 24 includes a query 26 to determine whether the chest pain is radiating toward the back. If not, “none” is marked by placing the cursor 28 on the “none” legend 30 for that answer and activating the choice (as by clicking a mouse button, if the cursor is moved by a mouse). The communication device 18 then displays that answer and the user is free to move on to other questions.

[0085] If the health care professional determines that the patient has chest pain radiating toward the back, “yes” is marked by placing the cursor 28 on the “to back” legend 32 for that answer and activating the choice. Other choices not shown in Figure 2 are accessed by operating a scrolling button 34. Responsive to that answer, an icon 36 indicative of an increased medical risk is presented on the communication device 18. This icon 36 is displayed in Figure 3, and is a fire-shaped, brightly colored icon that contrasts by its larger size and brighter red and orange colors with other indicia on the template 24. The icon 36 is also visible in Figure 2, but is muted in color in Figure 2 because it is not activated. The icon 36 is present in muted form before it is activated so a health care professional will not overlook the inquiry that activates the icon 36 when necessary.

[0086] Upon activation of the icon 36, the health care professional can click on or otherwise query the icon 36. This might be done to find out what medical risk is presented or what additional medical care is necessary to reduce the medical risk resulting when the chest pain

presented by the patient is radiating toward the back. This query causes an additional care legend or message to be presented on the communication device 18, such as the pop-up legend 38 shown as Figure 4: "Recommendation: Consider the diagnosis of Thoracic Aortic Dissection (TAD). Measure bilateral arm blood pressure, if possible. Look at the X-ray specifically for signs of TAD (e.g. abnormal aortic contour, widening or mediastinum, deviation of the trachea or mainstem bronchi). Document your observations." Thus, additional diagnostic steps are recommended to evaluate whether a TAD is present. The health care professional also is strongly encouraged to document his observations so the fact that the possibility of a TAD was thoroughly and quickly evaluated can be verified.

**[0087]** The medical risk raised by the symptom of chest pain radiating toward the back is that a TAD will be missed, as this is a condition that sometimes is not found quickly enough when a chest pain complaint is evaluated. This fact was ascertained by reviewing the results of malpractice actions in which liability was found because a TAD allegedly should have been diagnosed soon enough to avoid further complications, but was not.

**[0088]** This medical risk has two components. One component is that a health care professional must recognize the possibility of a TAD very rapidly to reach the best possible patient outcome.

**[0089]** The other component is that, even if the health care professional quickly recognizes and properly evaluates the possibility of a TAD, but rules it out as inconsistent with other diagnostic indications, the pertinent facts must be documented in the patient's chart immediately. Even if the patient's condition has been properly evaluated as ruling out a TAD, an anomalous TAD could exist that would not have been recognized by even a skilled physician. Alternatively, the patient might not be

suffering from a TAD initially, but may develop this condition shortly after the diagnosis that no TAD is present. If the symptoms presented by the patient at the time of diagnosis are properly and quickly evaluated and documented, the best possible care has been given, and the health care professional will be able to show this fact by reference to the patient's chart.

[0090] The present invention addresses the need to quickly evaluate and document TAD in a patient presenting chest pain that radiates to the back. The template 24 responds to the selection of this characterization of the chest pain immediately by presenting a distinctive and unusual warning, here the fire icon 36, that additional diagnostic work is necessary to rule out an increased medical risk of a TAD in this instance. This information is presented only when it is needed, so if this condition is not presented there is no need to alarm or distract the medical health professional by presenting this information.

[0091] The present invention works equally well to signal the need for additional care, whether diagnostic or therapeutic, when other conditions posing an increased medical risk are presented.

### **Prompting System**

[0092] A useful component of the present system is a prompting system that suggests or prompts the health care provider to include the important or critical elements of documentation of a patient's particular medical condition in the medical record. This component of the invention contains some aspects of simple medical logic. For example, the critical elements of documentation for a patient with a laceration are not known until the specific location of the laceration is known. Once the health care provider indicates the location of the laceration, the red light green light

prompts then appear at the appropriate locations in the templated medical record.

**[0093]** Insurance company data and the scientific medical literature clearly indicate that poor medical record documentation, inadequate history taking and inadequate physical examinations are among the leading causes of medical errors, patient injuries and medical malpractice lawsuits. This part of the invention is designed to prompt health care practitioners to address factors in the history and physical examination that are critical to documenting a complete medical record, identifying important factors in the patient's history and physical examination, reduction in medical errors and resulting medical malpractice lawsuits.

**[0094]** The factors deemed critical to medical record documentation have been identified through an investigation by Daniel J. Sullivan, M.D., J.D., FACEP, into the scientific medical literature (multiple publications in the ED Legal Letter), and an analysis of over 100 malpractice lawsuits published in Dr. Sullivan's "High Risk Acute Care: The Failure to Diagnose).

**[0095]** The red light green light system are merely prompts; they are not mandatory. However, use of these prompts in a research setting, has led to an unprecedented level of documentation as demonstrated through published, juried, scientific publication (see Supplement to Annals of Emergency Medicine, October 2000 Volume 36 Number 4, Abstract # 216 entitled "On-Line Risk Management Combined With Template-Based Charting Improves the Documentation of Key Historical Data in Patients Presenting With Chest Pain."

**[0096]** In addition, the use of the electronic template format allows the application of medical logic. It is impossible to know what factors in the history and physical examination are essential in patient care without some initial input from the practitioner. Once the practitioner begins

entering information, the risk program responds by allowing previously invisible red lights, green lights to become visible. See Example 6 below.

[0097] The red light, green light prompts also assist the practitioner in considering the differential diagnosis. In the typical patient medical presentation, the patient first states a problem. Based upon this problem, or chief complaint, the practitioner then considers a list of possible diagnoses, called the differential diagnosis. This list of possible diagnoses guides the practitioner as to what questions to ask, what organ systems to evaluate, and which diagnostic tests to order. The prompts assist the practitioner in considering the diagnoses which are prone to being missed, or a particularly high-risk to the patient. The differential diagnosis each have a drop down list of risk factors, allowing the physician a method for immediate recall of difficult to remember historical items. This function is demonstrated in Figure 13 and 14.

#### **Key Information Icons**

[0098] Another aspect of the invention is immediate electronic access to critical information behind a "key information" icon, at various points throughout the many templates.

[0099] Medical practice is complex. Practitioners must remember or refer to a reference for a wide range of information. In actual practice, it is not possible to remember for an entire career, long lists of nerves with their specific function, long lists of tendons and how to test them, trauma scoring, croup scoring, Apgar scoring for the newborn, new standards of care and too many other lists, scores and other items to mention.

[0100] The simple fact is that practitioners need immediate reference to large amounts of diverse information that is often not



immediately available in text, or on line. In addition, the busy practitioner seldom has time for looking up reference information.

[0101] Therefore, based upon research and practice, Daniel J. Sullivan, M.D., J.D., FACEP has provided immediate access via key information icons to lists of critical information, anatomical drawings, scores of various kinds, updates on standards of care, tendon identification and testing.

[0102] For example Figure 10 demonstrates the extremity examination position of the shoulder injury electronic template. There are four key information icons in the gray area labeled extremity examination. The practitioner can place a cursor or touch mechanism over the labeled icons which will and with a single click demonstrate the anatomy of the shoulder (see Figure 11). Thus, the practitioner has immediate access to information which simply may not be available in many medical settings.

[0103] There are over 100 key icons in one exemplary system, providing a wide range of critical information for the medical practitioner.

### **Triage High Risk Alert**

[0104] When patients present to an emergency department with a medical problem, in most cases, they first see a nurse in an area outside of the department, called triage. Triage is the sorting of patients by severity of illness. There are several diagnoses which are so acute, that intervention must be immediate or the patient may suffer severe injury. It is critical that the staff in triage recognize this small group of acute emergencies and communicates this to the appropriate individuals, such as the physician on duty in the emergency department or the charge nurse. The group of diagnoses includes such things as the following: chest pain in a patient over 35 years of age; a patient presenting the a cold pulseless extremity; a child under 2 months of age with a fever, etc.

[0105] This invention provides the triage nurse with an electronic template which can include a drop down list of these high risk acute presentations. That part of the template contains a red light, green light prompt in order to obtain a high level of compliance with the use of this function. If the nurse chooses one of these high risk diagnoses, the program immediately pops up a warning indicating that immediate notification of the physician or charge nurse must occur. In this fashion, the combination of the red light, green light prompt and the high risk list assists the nurse in quickly identifying the acute emergencies and making the patient a high priority for treatment in the emergency department.

FOOTNOTES

### Example 1: Abdominal Pain

Patient Data	Medical Risk	Proposed Response
the patient is pregnant	A pregnant patient suffering from abdominal pain may have an ectopic pregnancy, which is not necessarily determinable by physical examination and may be misdiagnosed as another condition.	Perform an ultrasound study of the fetus and surrounding maternal tissue.
woman of child bearing age with abdominal pain	Patients reporting information inconsistent with pregnancy, such as abstinence from intercourse, recent menstruation, or the use of contraceptives often are nonetheless pregnant. When a pregnant person presents abdominal pain, the diagnosis of (cont'd)	Test for pregnancy

### Example 1: Abdominal Pain

Patient Data	Medical Risk	Proposed Response
	ectopic pregnancy should be considered.	
sudden onset of abdominal pain	A vascular event that requires quick treatment, such as abdominal aortic aneurysm (AAA), may have occurred. AAA is often overlooked, as it can be difficult to diagnose.	Test for a vascular event
The patient's abdominal pain radiates to the back or to the flank.	An AAA, which requires quick treatment, may have occurred.	Test for AAA

## Example 2: Neck Pain

Patient Data	Medical Risk	Proposed Response
Blunt spine injury less than eight hours before the time of diagnosis.	In a number of cases, liability has been found because the patient was diagnosed with a spinal cord injury several hours (but fewer than eight hours) after the injury, but methylprednisolone treatment to reverse the effects of spinal cord injury was not started early enough to improve the patient outcome.	Blunt spine injury is treated with high dose methylprednisolone if treatment is begun within eight hours of the injury. The literature does not demonstrate any benefit beyond eight hours. <ul style="list-style-type: none"> <li>• 30 mg/kg bolus administered IV over 15 min.</li> <li>• 45 min. pause</li> </ul> Maintenance infusion 5.4 mg/kg/hr for 23 hours
The patient is intoxicated with alcohol or other intoxicants.	The intoxication may mask the effects of cervical spinal cord injury or render the patient unable or unwilling to cooperate.  (cont'd)	Liberal ordering of the trauma C-Spine series is recommended in this setting.

## Example 2: Neck Pain

Patient Data	Medical Risk	Proposed Response
Neck pain, but no radiologic (i.e. bone) abnormality in the x-ray and no apparent neurological changes.	Spinal cord injuries do not always coincide with spine damage visible on x-rays or stable neurological changes. Transient neurologic changes may occur before the emergency department visit, and not be present in the emergency department. Spinal Cord Injury Without Radiological Abnormality (SCIWORA) is often very difficult to diagnose, sometimes with catastrophic results.	Don't rely solely on the absence of radiological abnormality and of present neurological symptoms. Look carefully at EMT (emergency medical technician) and nursing notes relating back to the time of the injury. If there is prior evidence of a neurologic sign or symptom, neurosurgical consultation, a period of observation or hospital admission are recommended.

### Example 3: Chest Pain

Patient Data	Medical Risk	Proposed Response
Chest Pain Radiating to the Back	This is a characteristic symptom of Thoracic Aortic Dissection (TAD), which is often missed in diagnosis because it often resembles other, less-critical conditions. TAD must be quickly diagnosed and treated to avoid death.	Consider the diagnosis of TAD <ul style="list-style-type: none"> <li>• Measure bilateral arm blood pressure, if possible.</li> <li>• Look at the x-ray specifically for signs of TAD (e.g. abnormal aortic contour, widening or mediastinum, deviation of the trachea or mainstem bronchi).</li> <li>• Document your observations.</li> </ul>
Chest pain PLUS: <ul style="list-style-type: none"> <li>• One major risk factor (smoking, hypertension, diabetes, family history (Hx), high cholesterol) or</li> <li>• A history of coronary artery disease</li> </ul>	Where chest pain is the only clinically apparent symptom of an acute myocardial infarction (AMI), that diagnosis is often prematurely ruled out in favor of other possible conditions (often due to coinciding symptoms of lesser problems, like (cont'd)	Do one of the following: <ul style="list-style-type: none"> <li>• Obtain cardiology consultation</li> <li>• Observation status to rule out myocardial infarction</li> <li>• Admit</li> </ul>

### Example 3: Chest Pain

Patient Data	Medical Risk	Proposed Response
	indigestion) and the patient is discharged. This delayed or missed diagnosis frequently results in death of the patient.	



#### Example 4: Headache

Patient Data	Medical Risk	Proposed Response
<p>This is reported as the worst headache of the patient's entire life.</p>	<p>This is a two-step risk.</p> <p>First, a very bad headache may be caused by a subarachnoid hemorrhage. Even though few severe headaches are caused by a subarachnoid hemorrhage, the patient outcome is poor unless the condition is quickly diagnosed and treated.</p> <p>Second, even if a 4<sup>th</sup> generation CT of the head is carried out, sometimes it will not be read as showing bleeding when the patient in fact has a subarachnoid hemorrhage.</p>	<p>(1) Order a non-infused CT of the head to rule out a subarachnoid hemorrhage.</p> <p>(2) Proceed with lumbar puncture even if the CT of the head is read as negative for bleeding.</p>

### Example 5: Testicular Pain

Patient Data	Medical Risk	Proposed Response
Abdominal pain, but no testicular pain	Torsion of the testicle is a difficult diagnosis, and is often missed, as often the patient's site of discomfort is in the abdomen, rather than the testicles.	Consider torsion in the differential diagnosis.
sudden onset of pain	Sudden onset of severe pain should rule out epididymitis, but often does not. Torsion testicle must be immediately diagnosed, since salvage of the testicle is only highly probable within six hours of the onset of pain.	Immediately consider the diagnosis of torsion testicle

Example 6		
Template		
Chest Pain	Practitioner indicates that chest pain radiates to the back. (see Figure 7)	Red light, green light, previously invisible now lights up next to bilateral blood pressures in the cardiovascular examination. Thus, the practitioner measures bilateral blood pressures, documents the result, specifically looking for and documenting the examination for a Thoracic Aortic Dissection.
Laceration Template	Practitioner indicates in the history that the laceration involves an extremity.	Red lights, green lights previously invisible in the extremity examination now light up. If the injury is in the extremity, critical documentation includes examination of the pulses, distal neurologic system and tendons.